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[REDACTED] ART UNIT

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1614

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/978,127	ZICKER ET AL.
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 1-38 is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. ____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> .	6) <input type="checkbox"/> Other: _____

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DETAILED ACTION

Claims 1-38 are presented for prosecution on the merits.

Claim Objections

1. Claims 2-5, 24-25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2-5 and 24-25 set forth the intended recipient of the diet formulation of claim 1. However, such a limitation does not further limit the structural/chemical aspects of the claimed diet formulation.

2. Claims 3, 7, 12, 17, 18, 19, 20-22, 23, 24-25, 31, 32, 33, 34-36, 37 are objected to because of the following informalities. Appropriate correction is required.

In claims 3 and 5, line 2, after “years”, --of age-- should be added.

In claim 7, lines 2-3, “selected from the group consisting ofor” is improper Markush terminology. The phrase should read --selected from the group consisting of....and--. Please see MPEP 2173.05(h).

In claim 12, lines 2-3, the phrase “a level of” should be deleted and replaced with --an effective amount of--.

In claim 17, line 2, after “fed”, --to-- should be added.

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In claim 18, lines 2-3, “selected from the group consisting ofor” is improper Markush terminology. The phrase should read --selected from the group consisting of....**and**--. Please see MPEP 2173.05(h). Also, in claim 18, line 3, after “fed”, --to-- should be added. Finally, in claim 18, line 3, after “acid”, a --,-- should be inserted.

In claim 19, line 1, after “wherein” , --effective-- should be added. Also, at line 2, after “fed”, --to-- should be added.

In claims 20-22, line 2, after “fed”, --to-- should be added.

In claim 23, page 12, line 1, --acid-- should be added after “alpha-lipoic--.

In claims 24-25, 28 and 30, line 2, after “years”, --of age-- should be added.

In claim 31, line 2, after “fed”, --to-- should be added.

In claim 32, lines 2-3, “selected from the group consisting ofor” is improper Markush terminology. The phrase should read --selected from the group consisting of....**and**--. Please see MPEP 2173.05(h). Also, in claim 32, line 3, after “fed”, --to-- should be added. Finally, an --s-- should be added at the end of “mixture” in line 3.

In claim 33, line 1, after “wherein”, -effective-- should be added. In line 2, an --s-- should be added at the end of “mixture” and after “fed”, --to-- should be added.

In claims 34-36, line 2, after “fed”, --to-- should be added.

In claim 37, line 2, before “antioxidant”, “enough” should be deleted and --effective amount(s) of-- should be added .

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Claim Rejections - 35 USC § 112

3. Claims 17, 19, 31, 33, 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 17 recites the limitation "Vitamin E" in line 1. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 17 recites the limitation "the diet" in line 2. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 19 recites the limitation "Vitamin C, l-carnitine, alpha-lipoic acid or mixtures thereof" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 31 recites the limitation "the Vitamin E" in line 1. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 33 recites the limitation "Vitamin C, l-carnitine, alpha-lipoic acid or mixtures thereof" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 37 recites the limitation "the nutritional requirements" in line 1. There is insufficient antecedent basis for this limitation in the claim.

10. Applicant is advised that should claim 1 be found allowable, claim 37 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight

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difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 1 and 37 are identical in scope because both claims set forth in a companion pet diet meeting ordinary nutritional requirements having effective amount of antioxidant. The limitations “to increase mental capacity” of the aged pet” and “to inhibit the deterioration of the mental capacity” of an aged pet are intended use limitations which are given little patentable weight in composition claims.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-5, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernotavicz 4,247,562.

Bernotavicz discloses that a typical dry pet food comprises starch, vegetable protein, animal protein, fat materials, vitamin, minerals and antioxidants. (Col. 1, lines 54-60). Bernotavicz also discloses an improved pet food diet that may include Vitamin E. Please see col. 5, lines 25-44.

With respect to the claimed intended use of the antioxidant, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and

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the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the pet food diet containing the antioxidant(s) would be capable of inhibiting the mental deterioration of the mental capacity of an aged pet or increasing the mental capacity of the aged pet.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

13. Claims 1-5, 8, 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Paluch 6,117,477.

Paluch discloses a multi component pet food product for old dogs or cats which is nutritionally complete according to American Feed Controls Officials standards, wherein the pet food product additionally comprises antioxidants such as provitamin A, Vitamin C, Vitamin E. Please see col. 4, lines 61-63; col. 6, lines 7-11; col.8, lines 28-31.

With respect to the claimed intended use of the antioxidant, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the pet food diet containing the antioxidant(s) would be capable of inhibiting the mental

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deterioration of the mental capacity of an aged pet or increasing the mental capacity of the aged pet.

14. Claims 1-8, 12, 13, 15, 19, 26, 27, 29, 33, 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Harper WO 00/44375.

Harper discloses dog or cat foodstuff containing antioxidants such as vitamin E or Vitamin C or mixtures thereof. The foodstuff contains an “antioxidant cocktail” to treat oxidative stress or disorders which have the component of oxidative stress such as aging and neurodegenerative disease in cats or dogs. Harper discloses methods of treating such disorders by feeding to the cat or dog the foodstuff containing the antioxidants. Please see the abstract, page 11, lines 6-15, page 13, lines 7-14, pages 14, lines 21-27.

The claims are anticipated by Harper because Harper discloses administration of identical antioxidants to a pet using Applicant’s claimed methods steps. Accordingly, inhibiting the deterioration of the mental capacity of the pet and increasing the mental capacity of the pet are inherent.

15. Claims 1, 2, 12, 13, 26, 27, 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Milgram et al. (abstract).

Milgram et al. disclose a method of feeding aged beagle dogs a canine diet consisting of broad spectrum antioxidants. The aged dogs learned tasks more quickly than the dogs on the control diet. Please see the abstract

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Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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18. Claims 6, 7, 9-11, 12-36, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernotavicz, supra and Paluch, supra in view of Sole et al., 6,232,346 and Weischer et al., 5,569,670.

Bernotavicz discloses that a typical dry pet food comprises starch, vegetable protein, animal protein, fat materials, vitamin, minerals and antioxidants. (Col. 1, lines 54-60). Bernotavicz also discloses an improved pet food diet that may include Vitamin E. Please see col. 5, lines 25-44.

Paluch discloses a multi component pet food product for old dogs or cats which is nutritionally complete according to American Feed Controls Officials standards, wherein the pet food product additionally comprises antioxidants such as provitamin A, Vitamin C, Vitamin E. Please see col. 4, lines 61-63; col. 6, lines 7-11; col. 8, lines 28-31.

Bernotavicz and Paluch do not disclose the Applicant's claimed antioxidants such as L-carnitine or alpha-lipoic acid, nor do they disclose a method for treating oxidative damage (claim 38), inhibiting the deterioration of mental capacity or increasing the mental capacity of an aged companion pet by administering antioxidants such as lipoic acid (claim 38); however, the Examiner refers to (1) Sole et al., which discloses a dietary supplement for administration to an animal such as dogs or cats, wherein the supplement may be used to treat a disease or state (functional deterioration) that is due to aging. The supplement comprises L-carnitine, vitamin E, Vitamin C and Selenium. Sole et al. further disclose that a good dietary intake of antioxidant is important for protection against free radical injury. Please see the abstract; col. 11, lines 62-67; col. 12, lines 45-50; col. 13, lines 10-28; col. 14, line 67 to col. 15, line 3; col. 15, lines 39-40

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and (2) Weischer et al., 5,569,670 which discloses pharmaceutical compositions comprising a combination of alpha-lipoic acid and Vitamin E for example, wherein the combination has detoxifying, immune-stimulating, cytoprotective effects. The compositions can be administered to animals such as cats. Please see the abstract; col. 11, lines 8-15; col. 13, lines 36-45.

It would have been obvious to one of ordinary skill in the art to modify the pet food compositions of Bernotavicz and Paluch to include the disclosed antioxidants of Sole for use in treating functional deterioration due to aging in dogs or cats because one of ordinary skill in the art would reasonably expect the resulting antioxidant-fortified pet food to be effective in providing the healthy as well as therapeutic advantages of the disclosed antioxidants. Such a modification would have been motivated by the reasoned expectation of producing an everyday pet food product that would serve to treat functional deterioration associated with aging in cats or dogs.

Moreover, it would have been obvious to one of ordinary skill in the art to further modify the pet food product of Bernotavicz, Paluch and Sole to additionally include alpha-lipoic acid as taught by Weischer for use in treating oxidative stress (claim 38) because one of ordinary skill in the art would reasonably expect the addition of alpha-lipoic acid to add detoxifying and cytoprotective effects to the pet food, thus protecting against oxidative stress or free radical injury.

Concerning the claimed limitation of inhibiting mental deterioration or increasing mental capacity in an aged pet, in view of Sole et al., one of ordinary skill in the art would reasonably

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expect the phrase "functional deterioration" to encompass deterioration in mental capacity.

Furthermore, in view of the advantageous and protective properties of the disclosed anti-oxidants, one of ordinary skill in the art would reasonably expect the antioxidant-fortified companion pet food product to increase the mental capacity of the aging animals.

Additionally, in addressing the claimed ages of the canine or feline, in view of the prior art, it would have been obvious and well within the capability of the skilled artisan to determine at what age the canine and feline would most benefit from the anti-oxidant-fortified pet food.

Finally, with respect to the claimed concentrations of antioxidants, concentration limitations are obvious absent evidence to the contrary. Please see Akzo v. E. I. Du Pont de Nemours, 1 USPQ 2d 1704 (Fed. Cir. 1987). Moreover, in view of the prior art, one of ordinary skill in the art would optimize dosage amounts so as to provide optimum health/therapeutic benefits.

19. Claims 8, 9-11, 14, 16, 17, 18, 20-25, 28, 30-32, 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harper, supra in view of Sole, supra and Packer et al. (Submitted in the IDS).

Harper as applied above.

Harper does not disclose methods of feeding cats and dogs foodstuffs containing other antioxidants such as L-carnitine and alpha-lipoic acid; however, the Examiner refers to (1) Sole et al., which discloses a dietary supplement for administration to an animal such as dogs or cats, wherein the supplement may be used to treat a disease or state (functional deterioration) that is due to aging. The supplement comprises L-carnitine, vitamin E, Vitamin C and Selenium. Sole et

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al. further disclose that a good dietary intake of antioxidant is important for protection against free radical injury. Please see the abstract; col. 11, lines 62-67; col. 12, lines 45-50; col. 13, lines 10-28; col. 14, line 67 to col. 15, line 3; col. 15, lines 39-40 and (2) Packer et al. , which discloses that alpha-lipoic acid is a good candidate as an antioxidant in neurodegenerative diseases. Please see page 244, first column, under Neurodegenerative Diseases ,beginning of third full paragraph. Packer et al. disclose that experimental results indicate that alpha-lipoic acid improved memory performance in aging mice. Please see page 244, second column, first full paragraph.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods and foodstuffs of Harper to also include antioxidants such as L-carnitine (taught by Sole) and alpha-lipoic acid (taught by Packer) because one of ordinary skill in the art would reasonably expect L-carnitine and alpha-lipoic acid to be equally effective in treating oxidative stress associated with aging in the cats and dogs of Harper.

Additionally, in addressing the claimed ages of the canine or feline, in view of the prior art, it would have been obvious and well within the capability of the skilled artisan to determine at what age the canine and feline would most benefit from the anti-oxidant-fortified pet food.

Finally, with respect to the claimed concentrations of antioxidants, concentration limitations are obvious absent evidence to the contrary. Please see Akzo v. E. I. Du Pont de Nemours, 1 USPQ 2d 1704 (Fed. Cir. 1987). Moreover, in view of the prior art, one of ordinary skill in the art would optimize dosage amounts so as to provide optimum health/therapeutic benefits.

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as can used

20. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harper, supra in view of Packer et al. (Submitted in the IDS).

Harper as applied above.

Harper does not disclose a method of treating oxidative stress by administering lipoic acid; however, the Examiner refers to Packer et al. , which discloses that alpha-lipoic acid is a good candidate as an antioxidant in neuordegenerative diseases. Please see page 244, first column, under Neurodegenerative Diseases ,beginning of third full paragraph. Packer et al. disclose that experimental results indicate that alpha-lipoic acid improved memory performance in aging mice. Please see page 244, second column, first full paragraph.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods and foodstuff of Harper to administer alpha-lipoic acid as an antioxidant because, in view of Parker's disclosure, one of ordinary skill in the art would reasonably expect alpha-lipoic acid and its antioxidant properties to treat the oxidative stress due to aging in the cats and dogs of Harper.

Double Patenting

21. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

22. Claims 1-37 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-37 of copending Application No. 09/922,632. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claim 38 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-22 and 26-36 of copending Application No. 09/922,632. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and USSN '632 claim a method for treating an aged companion pet by administering to the pet a diet meeting nutritional requirements said diet containing an antioxidant such as lipoic acid.

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The difference between the instant application and USSN '632 is that claims 12 and 26 of USSN '632 are broader and require the administration of an antioxidant whereas claim 38 of the instant application requires the administration of lipoic acid.

However, the scope of the claims of the instant application and the claims USSN '632 overlap because the claims of USSN '632 are broader and encompass the more limited claim 38 of the instant application. Furthermore, the dependent claims of USSN '632 set forth that lipoic acid may be one of the antioxidants that is administered to the pet.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-38 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

CM

May 5, 2002

Cybille Delacroix

Cybille Delacroix-Muirheid
Patent Examiner Group 1600